UNITED STATES DISTRICT COURT
DISTRICT OF MINNESOTA

BRENDA PEREZ, *Plaintiff*, vs. COLOPLAST CORP. AND COLOPLAST MANUFACTURING US, LLC., *Defendants.*	§	CASE NO.: _____ **COMPLAINT AND JURY TRIAL DEMAND**

COMPLAINT

Plaintiff BRENDA PEREZ ("Plaintiff") files this Complaint against Defendants, COLOPLAST CORP. and COLOPLAST MANUFACTURING US, LLC ("Defendants"), and alleges as follows:

INTRODUCTION

1. On September 2, 2013, Plaintiff, BRENDA PEREZ, was surgically implanted with an Aris Sling System ("Aris"), a pelvic mesh product and medical device designed, manufactured, and marketed by Defendants, in order to treat the symptoms of stress urinary incontinence. During the same procedure, Plaintiff was also surgically implanted with a Restorelle Y-Mesh Implant ("Restorelle") to treat the symptoms of vaginal vault prolapse.

2. Defendants' Restorelle was intended to treat vaginal vault prolapse, however, neither Plaintiff nor her physicians were warned that the Restorelle was defective and negligently designed and manufactured. Plaintiff, as a result of being surgically implanted with Defendants' unreasonably dangerous and defective Pelvic Mesh Products, has suffered, and continues to suffer,

debilitating injuries, as described further herein. Plaintiff brings this suit for damages related to those injuries.

PARTIES

3. Plaintiff BRENDA PEREZ is, and was at all times relevant to this action, a citizen and resident of Charlotte, Mecklenburg County, North Carolina.

4. Defendant COLOPLAST CORPORATION ("Coloplast Corp.") is a corporation organized and existing under the laws of the State of Delaware, maintaining its principal place of business at 1601 West River Road North, Minneapolis, Minnesota 55411.

5. Defendant COLOPLAST MANUFACTURING US, LLC ("Coloplast US") is a limited liability corporation organized and existing under Delaware law, maintaining its principal place of business at 1940 Commerce Drive, North Mankato, Minnesota 56002. Its registered office is 560 Park Street, #6, St. Paul, Minnesota 55103. Coloplast US is a wholly owned subsidiary of Coloplast Corp.

JURISDICTION AND VENUE

6. This Court has jurisdiction over this civil action pursuant to 28 U.S.C. §1332(a), as the amount in controversy exceeds $75,000 and the Plaintiff is a citizen of a different state than one or more of the Defendants.

7. At all times material hereto, Defendants were engaged in the business of developing, manufacturing, designing, licensing, promoting, marketing, distributing, testing, warranting and/or selling in interstate commerce throughout the United States, including the State of North Carolina, either directly or indirectly, Pelvic Mesh Products intended to treat stress urinary incontinence and/or pelvic organ prolapse, including the Aris and Restorelle that were implanted into Plaintiff.

8. Venue in this district for pretrial proceedings in this civil action is proper under 28 U.S.C. §1391, as Defendant, Coloplast Corp. maintains its principal place of business in Minneapolis, Minnesota. Venue is further appropriate as Defendant, Coloplast US maintains its registered office in St. Paul, Minnesota.

9. Defendants are subject to *in personam* jurisdiction in the U.S. District Court, District of Minnesota, because Defendant's principal place of business is within the District of Minnesota. As such, Defendants have sufficient minimum contacts in Minnesota or otherwise intentionally avails itself to the Minnesota market through, without limitation, its advertisement, promotion, marketing, sales and/or distribution and other business activities, so as to render the exercise of jurisdiction over it by the U.S. District Court, District of Minnesota, consistent with traditional notions of fair play and substantial justice.

DEFENDANTS' PELVIC MESH PRODUCTS

10. At all times material to this action, Defendants designed, patented, manufactured, packaged, labeled, marketed, sold, and distributed a line of pelvic mesh products, including the Aris and Restorelle, the products implanted into Plaintiff. These products were designed primarily for the purpose of treating stress urinary incontinence and pelvic organ prolapse, respectively. These products were cleared, not approved, for sale in the United States after the Defendants made assertions to the Food and Drug Administration of "Substantial Equivalence" under Section 510(k) of the Food, Drug and Cosmetic Act; this process does not require the applicant to prove safety or efficacy.

11. The products include those known as T-Sling-Universal Polypropylene Sling, Aris-Transobturator Sling System, Supris-Suprapubic Sling System**,** Novasilk-Synthetic Flat Mesh, Exair-Prolapse Repair System, Restorelle, Smartmesh, Omnisure, and Minitape as well as any

variations of these products and any unnamed Coloplast pelvic mesh product designed and sold for similar purposes, inclusive of the instruments and procedures for implementation. In addition, Coloplast manufactures, distributes, and sells products made of biologic materials known as Suspend-Tutoplast Processed Fascia Lata and Axis-Tutoplast Processed Dermis as well as any variations of these products and any unnamed Coloplast Pelvic Mesh Product designed and sold for similar purposes, inclusive of the instruments and procedures for Implementation.

12. These products are collectively referenced as Defendants' "Pelvic Mesh Products" or "Products."

FACTUAL BACKGROUND

13. At all relevant times, Defendants were in the business of developing, designing, licensing, manufacturing, distributing, selling, marketing, advertising, delivering, and introducing into interstate commerce, including, *inter alia,* within the United States and within the states of North Carolina and Minnesota, either directly or indirectly through third parties, subsidiaries or related entities, pelvic mesh products, including the Aris and Restorelle, the pelvic mesh products at issue, herein.

14. At all relevant times, the Aris was intended to be used, and for Plaintiff was used, to treat stress urinary incontinence.

15. At all relevant times, the Restorelle was intended to be used and for Plaintiff was used to treat vaginal vault prolapse, a type of pelvic organ prolapse.

16. Stress urinary incontinence is a type of incontinence characterized by leakage of urine during moments of physical stress, such as coughing, laughing, or sneezing.

17. Vaginal vault prolapse occurs when the upper portion of the vagina loses its normal shape and sags or drops down into the vaginal canal or outside of the vagina.

18. Surgical mesh, including mesh used in the Pelvic Mesh Products, is a medical device that is generally used to repair weakened or damaged tissue. In urogynecologic procedures, surgical mesh is permanently implanted to reinforce the weakened vaginal wall to repair pelvic organ prolapse or to support the urethra to treat stress urinary incontinence. Most pelvic mesh products, including Aris and Restorelle, are comprised of non-absorbable, synthetic, monofilament polypropylene mesh.

19. Despite claims that polypropylene mesh is inert, the scientific evidence shows that this material, as implanted in Plaintiff, is biologically incompatible with human tissue and when used as a woven or knitted alloplastic textile prosthetic mesh for pelvic floor repair, polypropylene and other surgical polymers promote a severe foreign body reaction and chronic inflammatory response in a large subset of the population implanted with Defendants' Pelvic Mesh Products. This "host defense response" by a woman's pelvic tissues promotes degradation of the polypropylene mesh and the pelvic tissue, and causes chronic inflammation of the pelvic tissue, shrinkage or contraction of the mesh leading to nerve entrapment, further inflammation, a chronic infectious response, and chronic pain. It also can cause new onset painful sexual relations, significant urinary dysfunction, vaginal shortening, and anatomic deformation, and can contribute to the formation of severe adverse reactions to the mesh.

20. When these Pelvic Mesh Products are inserted into the female body, according to the manufacturers' instructions, it creates a non-anatomic condition in the pelvis leading to chronic pain and functional disabilities.

21. In 1996, the FDA cleared the first pelvic mesh products for us in the treatment of stress urinary incontinence ("SUI") and pelvic organ prolapse ("POP"). These products included products manufactured, marketed, and distributed by Defendants. These products were cleared by

the FDA under the abbreviated 510(k) clearance process. Section 510(k) provides for marketing of a medical device if the device is deemed "substantially equivalent" to other predicate devices marketed before May 28, 1976. No formal review for safety or efficacy is required, and no formal review for safety or efficacy was ever conducted in regard to the pelvic mesh products, including the Pelvic Mesh Product at issue in this case.

22. On February 8, 2001, Mentor announced the purchase of Porges S.A. ("Porges"), a subsidiary of Sanofi-Synthelabo ("Sanofi"). At the time, Porges held the leading market share for urological products in France and held a strong position throughout Europe as one of the largest manufacturers of urological products, supplying a complete range of products including pelvic mesh products.

23. In May 2005, Mentor announced the U.S. launch of its new Aris™ Trans-Obturator Tape. According to Mentor's launch reports, "specifically designed to utilize Mentor's patented Trans-Obturator Technique (T.O.T.™), Aris represents the newest technical achievement and advanced generation of trans-obturator slings for the treatment of stress urinary incontinence in women." "The introduction of Aris furthers Mentor's position as a pioneer of the trans-obturator method for treating stress incontinence in women," commented Joshua H. Levine, President and Chief Executive Officer of Mentor Corporation. "We are committed to driving innovation in the field of women's health to provide better solutions for physicians and the patients they serve."[1] FDA registration lists its proprietary device as "Mentor Aris Trans-Obturator Tape and Surgical Kit."

24. On October 12, 2005, ABISS and Mentor entered into a number of agreements pursuant to which ABISS licensed a number of ABISS' products to Mentor, which were thereafter

[1] Analytic Biosurgical Solutions ("ABISS").

marketed by Mentor under its trademarks, including its Aris trademark. On June 2, 2006, Mentor sold its surgical, urological, clinical and consumer healthcare business segments to Coloplast for $461,145,398, including inter alia, Mentor's October 12, 2005, agreements with ABISS and Mentor's Aris and Novasilk Pelvic Mesh Products.

25. At all times, the product marketed and sold in the United States as "Mentor Aris Trans-Obturator Tape and Surgical Kit" was manufactured by ABISS and, at all times after October 2, 2006, the product "Mentor Aris Trans-Obturator Tape and Surgical Kit" was exclusively marketed and sold in the United States by Coloplast Corp. from its principal place of business in Minneapolis, Minnesota.

26. ABISS is registered with the FDA, Registration Number 3004756681, as the manufacturer of "Mentor Aris Trans-Obturator Tape and Surgical Kit."

27. On December 5, 2005, Mentor obtained 510(k) clearance for Mentor NovaSilk Mesh. Mentor NovaSilk Mesh is a permanent, synthetic knitted propylene mesh that is square in shape and is a sterile, single use device. The Mentor NovaSilk Mesh obtained 510(k) clearance based on substantial equivalence in material, function, performance, and design to the Gynemesh Prolene Soft (Polypropylene) Mesh cleared under 510(k) K013718 and knitted polypropylene already in use under Mentor's Aris Sling cleared under 510(k) K050148. Joshua H. Levine, President and Chief Executive Officer of Mentor Corporation commented, "The addition of NovaSilk to Mentor's expanding portfolio of women's health products for pelvic organ prolapse or stress urinary incontinence reinforces the commitment of our urology franchise to surgeons and the patients they serve by providing high quality product offerings and customer service and support."

28. Coloplast A/S received 510(k) clearance for the Supris Retropubic Sling system 510(k) K111233 in June 2011, as a device substantially equivalent to the Mentor Aris Suprapubic Surgical Kit.

29. On July 13, 2011, the FDA issued a new warning regarding serious complications associated with pelvic mesh products, such as the Pelvic Mesh Products manufactured, marketed, and distributed by Defendants. In this warning, the FDA indicated that "serious complications associated with surgical mesh for transvaginal repair of POP are **not rare.**" (Emphasis in the original). The FDA had also received increased reports of complications associated with the pelvic mesh products used in both pelvic organ prolapse and stress urinary incontinence cases.

30. The FDA Safety Communication also stated, "Mesh contraction (shrinkage) is a previously unidentified risk of transvaginal POP repair with mesh that has been reported in the published scientific literature and in adverse event reports to the FDA . . . Reports in the literature associate mesh contraction with vaginal shortening, vaginal tightening and vaginal pain." (Emphasis in original).

31. The FDA Safety Communication further indicated that the benefits of using pelvic mesh products instead of other feasible alternatives did not outweigh the associated risks. Specifically, the FDA Safety Communication stated: "it is not clear that transvaginal POP repair with mesh is more effective than traditional non mesh repair in all patients with POP and it may expose patients to greater risks."

32. Contemporaneously with the Safety Communication, the FDA released a publication titled "Urogynecologic Surgical Mesh: Update on the Safety and Effectiveness of Transvaginal Placement for Pelvic Organ Prolapse" (the "White Paper"). In the White Paper, the FDA noted that published, peer-reviewed literature demonstrates that "[p]atients who undergo

POP repair with mesh are subject to mesh-related complications that are not experienced by patients who undergo traditional surgery without mesh."

33. The FDA summarized its findings from its review of the adverse event reports and applicable literature stating that it "has NOT seen conclusive evidence that using transvaginally placed mesh in POP repair improves clinical outcomes any more than traditional POP repair that does not use mesh, and it may expose patients to greater risks." (Emphasis in original).

34. The White Paper further stated that "these products are associated with serious adverse events ... Compounding the concerns regarding adverse events are performance data that fail to demonstrate improved clinical benefit over traditional non-mesh repair." In its White Paper, the FDA advises doctors to, *inter alia,* "[r]ecognize that in most cases POP can be treated successfully without mesh thus avoiding the risk of mesh related complications." The White Paper concludes by stating that the FDA "has identified serious safety and effectiveness concerns over the use of surgical mesh for the transvaginal repair of pelvic organ prolapse."

35. On August 25, 2011, Public Citizen, a consumer advocacy group, submitted a petition to the FDA seeking to ban the use of pelvic mesh products in pelvic repair procedures. In its Petition, Public Citizen warned that pelvic mesh products should be recalled because they offer no significant benefits but expose patients to serious risks and the potential for permanent life-altering harm. Joining Public Citizen as co-petitioners were Dr. L. Lewis Wall, a professor of obstetrics and gynecology at Washington University in St. Louis, and Dr. Daniel S. Elliott, a urologic surgeon specializing in female urology at the Mayo Clinic in Rochester, Minnesota.

36. In a December 2011, Joint Committee Opinion, the American College of Obstetricians and Gynecologists ("ACOG") and the American Urogynecologic Society ("AUGS")

also identified physical and mechanical changes to the transvaginal mesh inside the body as a serious complication associated with transvaginal mesh, stating:

> There are increasing reports of vaginal pain associated with changes that can occur with mesh (contraction, retraction, or shrinkage) that result in taut sections of mesh…Some of these women will require surgical intervention to correct the condition, and some of the pain appears to be intractable.

37. The ACOG/AUGS Joint Committee Opinion also recommended, among other things, that "[p]elvic organ prolapse vaginal mesh repair should be reserved for high-risk individuals in whom the benefit of mesh placement may justify the risk."

38. As is known to the Defendants, the risks associated with POP repair are the same as SUI repair. However, the data regarding the magnitude and frequency of these known risks are not as developed as the data on POP repair. The FDA recognized this, as demonstrated by its Section 522 Orders issued to manufacturers of pelvic mesh products used to treat SUI in January of 2012.

39. In September 2011, the FDA acknowledged the need for additional data and noted in "Surgical Mesh For Treatment of Women with Pelvic Organ Prolapse and Stress Urinary Incontinence" that the literature and information developing on SUI repair with Pelvic Mesh Products "indicate that serious complications can occur ... [and] a case can be made for additional premarket and/or post market studies to better address the risk/benefit of all mesh products used for SUI."

40. After the 2011 FDA notification that mesh complications from POP repairs were "not rare," a 2013 article was published that stated: "as outlined in the FDA notifications, patients should be forewarned that some transvaginal mesh complications are life altering and might not always be surgically correctable. Furthermore, that study noted that "the women who received both MUS and TM represented a complicated surgical group. Fifteen women (43%) required MUS

takedown concurrently with prolapse mesh excision. Two-thirds of these women had associated chronic pelvic pain and vaginal pain, in addition to their urinary symptoms."

41. On April 16, 2019, the FDA ordered all manufacturers of surgical mesh intended for transvaginal repair of anterior compartment prolapse ("cystocele") to stop selling and distributing their products immediately. In fact, the FDA has determined that the manufacturers, Boston Scientific and Coloplast specifically, have not demonstrated reasonable assurance of safety and effectiveness for these devices, which is the premarket standard that now applies to them since the agency reclassified them into class III (high risk) in 2016.[2]

42. Defendants did not, and have not, adequately studied the extent of the risks associated with their Pelvic Mesh Products. In January 2012, the FDA recognized the risk to women and mandated additional studies to further investigate these risks.

43. Defendants knew of should have known that their Pelvic Mesh Products unreasonably exposed patients to the risk of serious harm while conferring no benefit over available feasible alternatives that do not involve the same risks. At the time Defendants began marketing the Aris and Restorelle, Defendants were aware that the Aris and Restorelle were associated with each and every one of the adverse events communicated by the FDA in its July 13, 2011, safety communication. Despite claims that polypropylene mesh is inert, the scientific evidence shows that this material, as implanted in Plaintiff, is biologically incompatible with human tissue and when used as a woven or knitted alloplastic textile prosthetic mesh for pelvic floor repair, polypropylene and other surgical polymers promote a severe foreign body reaction and chronic inflammatory response in a large subset of the population implanted with Defendants' Pelvic Mesh Products, including the Aris and Restorelle, the product at issue herein. This "host

[2] www.fda.gov/medical-devices/implants-and-prosthetics/urogynecologic-surgical-mesh-implants.

defense response" by a woman's pelvic tissues promotes degradation of the polypropylene mesh and the pelvic tissue, causes chronic inflammation of the pelvic tissue, causes shrinkage or contraction of the mesh leading to nerve entrapment, further inflammation, chronic infectious response and chronic pain, cause new-onset painful sexual relations, significant urinary dysfunction, vaginal shortening and anatomic deformation, and can contribute to the formation of severe adverse reactions to the polypropylene mesh.

44. The FDA defines both "degradation" and "fragmentation" as "device problems" to which the FDA assigns a specific "device problem code." "Material Fragmentation" is defined as an "[i]ssue associated with small pieces of the device breaking off unexpectedly" and "degraded" as an "[i]ssue associated with a deleterious change in the chemical structure, physical properties, or appearance in the materials that are used in device construction."

45. Defendants made the following statements regarding their products:

> (Aris has) Low rate of particle release from the sling – **minimizes increase in inflammatory response**. Atraumatic, smooth edges allow for easy passage during implantation. Macroporous design allows for optimal tissue integration. (Emphasis added).

46. Contrary to Defendants' assertions that its products minimize increase in inflammatory response:

A. In September 2009, results from a study were published in the BMC Women's Health relating to the comparison of host response and complications in patients implanted with Coloplast's Aris. Implants from the Aris group showed an **increase risk of erosion which was quantified at 4%**. Kaelin-Gambirasio, I, *Complications associated with transobturator sling procedures: analysis of 233 consecutive cases with a 27 months follow-up.*[3]

[3] BMC Womens Health. 2009 Sep 25; 9:28.

B. In September 2012, results from a study were published in the World Journal of Urology relating to the comparison of TVT vs TOT slings. 15 of 71 patients suffered adverse events including infection and erosion, **two thirds of which were implanted with the Aris**. Wadie BS, *TVT versus TOT, 2-year prospective randomized study*.[4]

47. Defendants made the following statements regarding their products:

> Novasilk is one of the lightest weight, thinnest meshes on the market, which translates into a more conforming mesh that may **reduce cases of inflammation, infection, or erosion** by having less implanted material.

48. Contrary to Defendants' assertions that its products are resistant to significant inflammation, infection, or erosion:

A. Complications from mesh placement for pelvic organ prolapse include among other adverse events: acute and chronic infection, tissue contraction due to mesh shrinkage, erosion of the mesh into adjacent structures, and dyspareunia. [painful sexual intercourse]. Cosson, M., et al., *Mechanical properties of synthetic implants used in the repair of prolapse and urinary incontinence in women: which is the ideal material?* Int Urogynecol J Pelvic Floor Dysfunct, 2003. 14(3): p. 169-78; discussion 178. Jones, K.A., et al., *Tensile properties of commonly used prolapse meshes.* Int Urogynecol J Pelvic Floor Dysfunct, 2009. 20(7): p. 847-53. Margulies, R.U., et al., *Complications requiring reoperation following vaginal mesh kit procedures for prolapse.*[5]

B. Erosion can be defined as the mesh wearing, or slowly grinding through the vaginal wall. This is a serious complication and moreover, there is evidence

[4] World J Urol. 2012 Sep 26.
[5] AM J Obstet Gynecol, 2008. 199(6): p. 678 et-4.

that meshes shrink *in vivo* leading to increased stiffness, pain and poor restoration of the normal properties of the vagina. Dora, C.D., et al., *Time dependent variations in biomechanical properties of cadaveric fascia, porcine dermis, procine small intestine submucosa, polypropylene mesh and autologous fascia in the rabbit model: implications for sling surgery*. J Urol, 2004. 171(5): p. 1970-3.

C. Larger pores within polypropylene mesh materials, allowing macrophage and leukocyte migration, reduce infection. Birch C, Fynes MM. The role of synthetic and biological prosthesis in reconstructive pelvic floor surgery. *Curr Opin Obstet Gynecol.* 2002; 14:527-595. 22. Govier FE, Kobashi KC, Kozlowski PM, Kuznetsov DD, Begley SJ, McGonigle KF, et al. High complication rate identified in sacrocolpopexy patients attributed to silicone mesh. *J Ural.* 2005; 65:1099-1103.

D. In a study published in August 2012, Defendants' Novasilk was compared to other polypropylene on the market relating structural properties. Novasilk was found to have less porosity and increased stiffness than several of the other studied products supporting clinical observations among Plaintiffs' surgeons and the causative conclusion that properties of Defendants' mesh led to Plaintiffs' complications. Feola A, *Characterizing the ex vivo textile and structural properties of syntheticprolapse mesh products.* Int Urogynecol J. 2012 Aug 11.

49. Defendants' Pelvic Mesh Products, including the Aris and Restorelle products at issue and their predecessor products, including Novasilk, were and are unreasonably susceptible

to degradation and fragmentation inside the body; shrinkage or contraction inside the body; intense foreign body reaction; chronic inflammatory response; chronic wound healing; chronic infections in and around the mesh fibers; and nerve entrapment. Defendants knew or should have known of these serious risks and should have, therefore, warned physicians and patients regarding these risks; to the extent they were known or knowable.

50. To this day, the Aris and Restorelle continue to be marketed to the medical community and to patients as safe, effective and reliable medical devices, implanted by safe, effective and minimally invasive surgical techniques, and as safer and more effective as compared to available feasible alternative treatments of pelvic organ prolapse and stress urinary incontinence, and other competing products.

51. Defendants omitted and downplayed the risks, dangers, defects, and disadvantages of their pelvic mesh products, including the Aris and Restorelle products at issue, and advertised, promoted, marketed, sold and distributed their pelvic mesh products, including the Aris and Restorelle, the products at issue, as safe medical devices when Defendants knew or should have known that the products were not safe for their intended purposes, and that the products would cause, and did cause, serious medical problems, and in many patients, including Plaintiff, catastrophic injuries. Further, while some of the problems associated with the pelvic mesh products, including the Aris and Restorelle, were made known to physicians, the magnitude and frequency of these problems were not disclosed and were hidden from physicians.

52. Contrary to Defendants' representations and marketing to the medical community and to the patients themselves, their products, including the Aris and Restorelle, the product at issue, have high rates of failure, injury, and complications, fail to perform as intended, require frequent and often debilitating re-operations, and have caused severe and irreversible injuries,

conditions, and damage to a significant number of women, including the Plaintiff, making them defective under the law.

53. The specific nature of the Products' defects includes, but is not limited to, the following:

A. The use of polypropylene in the Pelvic Mesh Product and the adverse tissue reactions and host defense response that result from such material, causing adverse reactions and serious, permanent injuries, but not limited to, painful recurrent erosions and associated intractable pain;

B. The design of the Products to be inserted into and through an area of the body that is blood vessel rich, nerve dense, and bacteria laden leading to excessive blood loss and vascular damage, permanent nerve injury and associated chronic, intractable neuropathic pain, contaminated permanently-implanted mesh causing chronic infections, subclinical infections and biofilms, enhanced chronic inflammatory response, chronic wound healing with tissue destruction, as well as numerous other adverse reactions and serious and permanent injuries;

C. The use and design of arms and hooked anchors in the Products, which, when placed in the women, are likely to pass through contaminated spaces and that can injure major nerve routes in the pelvic region; and

D. The procedure to place the Products requires blindly placing the arms the device through the thigh and obturator fossa that can injure major nerves that contribute to sexual function, mobility, and to bowel and bladder function.

FACT SPECIFIC ALLEGATIONS

54. On September 2, 2013, at Novant Health Presbyterian Medical Center, 200 Hawthorne Lane, Charlotte, North Carolina 28204, William E. Porter, M.D. implanted Plaintiff BRENDA PEREZ with a Coloplast Aris System and the Coloplast Restorelle Y-Mesh (the "Devices"), medical devices designed, manufactured, and marketed by Defendants, for the treatment of stress urinary incontinence and pelvic organ prolapse, respectively. While the Devices were intended to treat SUI and POP, neither Plaintiff nor her physician were warned that the Devices were defective and negligently designed and manufactured, as discussed further herein.

55. The Devices implanted in Plaintiff were in the same or substantially similar condition as they were when they left Defendants' possession, and in the condition directed by and expected by Defendants.

56. Plaintiff's treating physician, William E. Porter, M.D., implanted the Devices properly and appropriately.

57. On January 16, 2019, at Novant Health Presbyterian Medical Center located in Charlotte, North Carolina, after suffering from severe pelvic pain and worsening stress urinary incontinence, William E. Porter, M.D. performed additional surgery as the Aris had eroded into vaginal canal and needed to be removed to avoid any further damage.

58. On April 25, 2019, at Novant Health Presbyterian Medical Center located in Charlotte, North Carolina, due to vaginal and rectal bleeding and examination, William E. Porter,

M.D. performed additional surgery as the Restorelle had eroded into vaginal canal and needed to be removed to avoid any further damage

59. Neither Plaintiff nor her physician were warned that the Devices were unreasonably dangerous, even when used exactly as intended by Defendants pursuant to Defendants' instructions for use. To the contrary, Defendants promoted, marketed, and sold their Pelvic Mesh Products, including the Devices implanted in Plaintiff (and thousands of women like Plaintiff) to healthcare providers as a safe alternative to other procedures that did not incorporate the Defendants' Pelvic Mesh Products.

60. Had Defendants properly disclosed the risks associated with the Devices implanted in Plaintiff for transvaginal use, Plaintiff would not have agreed to undergo treatment incorporating the Devices. On information and belief, had Plaintiff's implanting physician, William E. Porter, M.D., been adequately and properly warned, he would have advised Plaintiff of the risks as part of her informed consent discussion and/or would have recommended a different treatment or no treatment at all.

61. As a direct and proximate result of having the Devices implanted in her, Plaintiff has experienced significant mental and physical pain and suffering, has sustained permanent injury which includes or more likely than not may include any of the following: pudendal neuralgia, obturator neuralgia, pelvic floor tension myalgia, hip adductor myalgia, complex regional pain syndrome, erosion, recurrent urinary tract infections, interstitial cystitis, chronic dyspareunia, bowel and bladder dysfunction, and anorectal pain will likely undergo medical treatment and procedures, has suffered financial or economic loss, including, but not limited to, obligations for medical services and expenses, and/or lost income, and other damages.

62. The injuries suffered by Plaintiff were caused by the Defendants' wrongful acts, omissions, and fraudulent representations.

DISCOVERY RULE

63. Plaintiff could not have reasonably discovered the occasion, manner and/or means by which Defendants' breach of duty occurred until within six years of the filing of this complaint. Further, Plaintiff did not and could not have discovered through the exercise of reasonable diligence, including consultations with her physicians, the existence of her legal cause of action or the injuries caused by Defendants' breach of duty and/or defective products until within six years of the filing of this complaint. Defendants continue to deny that their Pelvic Mesh Products are defective and cause injuries, such as those suffered by Plaintiff, and continue to manufacture, market, and sell all or some of the Pelvic Mesh Products at issue. Any applicable statute of limitations has been tolled by the Defendants' knowledge, active concealment, and continued denial of material facts known by Defendants, who had a duty to disclose, and/or by the application of the discovery rule.

64. Minn. Stat. 541.05(6) state that "for relief on the ground of fraud, in which case the cause of action shall not be deemed to have accrued until the discovery by the aggrieved party of the facts constituting the fraud."

CAUSES OF ACTION

COUNT I: NEGLIGENCE

65. Plaintiff re-alleges and incorporates by reference each of the foregoing paragraphs of this complaint as is fully set forth herein and further alleges as follows:

66. At all times herein mentioned, Defendants were engaged in the business of researching, manufacturing, licensing, fabricating, designing, labeling, distributing, using, supplying, selling, marketing, warranting, packaging, and advertising the Devices.

67. Defendants owed to Plaintiff and the public a duty to act reasonable and to exercise ordinary care in pursuit of the activities mentioned above. Defendants breached said duty of care.

68. At all times relevant hereto, Defendants owed to Plaintiff and the public a duty to act reasonably and to exercise ordinary care with respect to the safe, legal, and proper manufacture, license, design, formulation, distribution, production, processing, assembly, testing, inspection, research, marketing, labeling, packaging, preparation for use, issuance of warnings with respect to use, promotion, advertising, sale, and safety monitoring of the Devices, and to adequately test and warn of the risk and dangers of the Devices, both before and after sale.

69. Additionally, Defendants owed to Plaintiff and the public a duty to provide accurate, reliable, complete, and truthful information regarding the safety and dangerous propensities of the Devices manufactured, used, distributed, and/or supplied by them, as well as to provide accurate, reliable, complete, and truthful information regarding the failure of the Devices to perform as intended or as an ordinary consumer would expect.

70. At all times relevant hereto, Defendants breached the aforementioned duties in that Defendants negligently and carelessly manufactured, fabricated, designed, licensed, produced, compounded, assembled, inspected or failed to inspect, tested or failed to test, warned or failed to warn of the health hazards, labeled, distributed, handled, used, supplied, sold, marketed, warranted, packaged, promoted, and advertised the Devices in that said Devices caused, directly and proximately, the injuries to Plaintiff through the failure of the Devices to perform as intended or

as an ordinary consumer would expect. Specifically, Defendants violated the duties of ordinary care and skill owed to Plaintiff in the following respects:

A. Failing to conduct adequate and appropriate testing of their Pelvic Mesh Products, including the Devices at issue, to ensure they were safe for implantation in the female pelvis;

B. Placing their Pelvic Mesh Products, such as the Devices at issue, on the market without first conducting adequate testing to determine possible side effects;

C. Placing their Pelvic Mesh Products, including the Devices at issue, on the market without adequate testing of its dangers to humans;

D. Failing to recognize the significance of the medical literature, their own testing, and/or the testing of, and information regarding pelvic mesh products such as the Devices at issue, when said literature/testing evidenced such products' potential harm to humans;

E. Failing to appropriately and promptly respond to the medical literature, their own testing, and/or the testing of, and information regarding pelvic mesh products such as the Devices at issue, when said literature/testing evidenced such products' potential harm to humans;

F. Failing to promptly and adequately warn of their Pelvic Mesh Products', such as the Devices at issue, to be harmful to humans;

G. Failing to promptly, adequately, and appropriately recommend testing and monitoring of pelvic mesh product patients, including patients implanted with the Devices at issue, in light of the knowledge that such products had the potential to be harmful to humans;

H. Failing to properly, appropriately, and adequately monitor the post-market performance of Defendants' Pelvic Mesh Products, including the Devices at issue, as well as said products' effects on patients;

I. Concealing from the FDA, the National Institutes of Health, the general medical community and/or physicians, their full knowledge and experience regarding the potential that Defendants' Pelvic Mesh Products, including the Devices at issue, could be harmful to humans;

J. Promoting, marketing, advertising, and/or selling their Pelvic Mesh Products, including the Devices at issue, for use on patients given their knowledge and experience of their Pelvic Mesh Products' potential harmful effects;

K. Failing to withdraw their Pelvic Mesh Products, including the Devices at issue, from the market, restrict their use, and/or adequately warn of such products' potential dangers given their knowledge of the potential for its harm to humans;

L. Failing to fulfill the standard of care required of a reasonable, prudent, urogynecological medical device manufacturer engaged in the design, manufacturer, and marketing of such products, including the Devices at issue;

M. Placing and/or permitting the placement of their Pelvic Mesh Products, including the Devices at issue, into stream of commerce without warnings of the potential for said products to be harmful to humans and/or without properly warning of the dangerousness of said products;

N. Failing to disclose to the medical community in a timely and appropriate manner facts relative to the potential of Defendants' Pelvic Mesh Products, including the Devices at issue, to be harmful to humans;

O. Failing to respond or react promptly and appropriately to reports of their Pelvic Mesh Products, including the Devices at issue, causing harm to patients;

P. Disregarding the safety of users and consumers of the Devices at issue, as well as their other Pelvic Mesh Products, including Plaintiff, by failing to adequately warn of said products' potential harm to humans;

Q. Disregarding the safety of users and consumers of the Devices at issue, as well as their other Pelvic Mesh Products, including Plaintiff, and/or her physicians, under the circumstances by failing to withdraw said products from the market and/or restricting their usage;

R. Disregarding publicity, government and/or industry studies, information, documentation, recommendations, consumer complaints, and reports and/or other information regarding the hazards of pelvic mesh products and their potential harm to humans;

S. Failing to exercise reasonable care in informing physicians and/or hospitals using Defendants' Pelvic Mesh Products, including the Devices at issue, about their knowledge regarding said products' potential harm to humans;

T. Failing to remove their Pelvic Mesh Products, including the Devices at issue, from the stream of commerce;

U. Failing to test their Pelvic Mesh Products, including the Devices at issue, properly and/or adequately so as to determine their safety for use;

V. Promoting their Pelvic Mesh Products, including the Devices at issue, as safe and/or safer than other comparative methods/products;

W. Promoting their Pelvic Mesh Products, including the Devices at issue, on websites aimed at creating user and consumer demand;

X. Failing to conduct and/or respond to post-marketing surveillance of complications and injuries resulting from their Pelvic Mesh Products, including the Devices at issue;

Y. Failing to use due care under the circumstances; and

Z. Failing to monitor, analyze, and report to the FDA, medical community, their product users, and/or physicians and/or hospitals, adverse post-surgical outcomes stemming from the use of their Pelvic Mesh Products, including the Devices at issue.

71. Defendants' acts constitute violations of the duty of care and skill owed by Defendants to Plaintiff.

72. Plaintiff used and was implanted with Defendants' Pelvic Mesh Products, the Devices, that was reasonably foreseeable.

73. As the direct and proximate result of Defendants' negligent and/or reckless and/or wanton breaches of their aforementioned duties with respect to the Devices, Plaintiff suffered the injuries and damages alleged herein.

WHEREFORE, said Plaintiff prays for judgment against Defendants.

COUNT II: STRICT LIABILITY – DESIGN AND MARKETING

74. Additionally, or in the alternative, if same be necessary, Plaintiff realleges and incorporates by reference each of the foregoing paragraphs 1 through 73 of this Complaint as if fully set forth herein and further alleges as follows:

75. A sustainable claim of design defect under Minnesota law must establish that (1) the product was in a defective condition, unreasonably dangerous for its intended use; (2) the defect existed when the product left the manufacturer's control; and (3) the defect proximately caused the plaintiff's injury. Westbrock v. Marshalltown Mfg. Co., 473 N.W.2d 352, 356 (Minn. Ct. App. 1991) (citing Bilotta v. Kelley Co., Inc., 346 N.W.2d 616, 624 (Minn. 1984))

76. Defendants were and are engaged in the business of selling their Pelvic Mesh Products, including the Devices aforementioned, in the States of North Carolina and Minnesota.

77. The Devices, manufactured, designed, marketed, promoted, and sold by Defendants, were expected to, and did, reach Plaintiff and her treating physician without substantial change in the condition in which they were sold. The Devices were defective at the time of manufacture, development, design, production, testing, inspection, endorsement, prescription, sale, and distribution, and at the time they left the possession of the Defendants.

78. Defendants are manufacturers and/or suppliers of pelvic mesh products, specifically the Devices at issue, and are strictly liable to Plaintiff for designing, creating, manufacturing, distributing, selling, and placing their Pelvic Mesh Products, specifically the Devises at issue, into the stream of commerce.

79. At the time Defendants' Pelvic Mesh Products, specifically the Devises at issue, left the possession of Defendants and entered the stream of commerce, the Devices at issue were in an unreasonably dangerous and defective condition.

80. First, Defendants' Pelvic Mesh Products, the Devices at issue, contained unreasonably dangerous design defects. Said defects include, but are not limited to:

A. The Devices were not reasonably safe as intended to be used;

B. The Devices had an inadequate design for the purposes of a pelvic mesh product intended to treat SUI and/or POP;

C. The Devices contained a defective design, which resulted in an unreasonably high probability of complications and/or injuries including but not limited to, erosion, mesh contraction, infection, fistula, inflammation, scar tissue, organ perforation, dyspareunia (pain during sexual intercourse), blood loss, neuropathic pain, and other acute and chronic nerve damage and pain, nerve damage, pelvic floor damage, and chronic pelvic pain,

D. The Devices' defective design resulted in a pelvic mesh product which had risks which exceeded the benefits of the Devices;

E. The Devices' defective design resulted in a pelvic mesh product which was more dangerous than the ordinary consumer would expect;

F. The Device failed to perform in a manner reasonably expected in light of their nature and intended function, and subjected Plaintiff to an unreasonable risk of harm beyond that contemplated by an ordinary person; and

G. Defendants' Pelvic Mesh Products, specifically the Devices at issue, were defective due to inadequate pre-market testing.

81. Defendants' Pelvic Mesh Products, specifically the Devices at issue, were also defective due to inadequate warnings or instructions, including, but not limited to:

A. Failing to provide adequate warnings and/or instructions when Defendants knew, or should have known, that their Pelvic Mesh Products, specifically the Devices at issue, created, among other things, erosion, mesh contraction, infection, fistula, inflammation, scar tissue, organ perforation, dyspareunia

(pain during sexual intercourse), blood loss, neuropathic pain, and other acute and chronic nerve damage and pain, nerve damage, pelvic floor damage, and chronic pelvic pain;

B. Failing to provide adequate initial warnings and post-marketing warnings or instructions after Defendants knew or should have known of the extreme risks associated with their Pelvic Mesh Products, including the Devices at issue, and continued to promote and sell those products in absence of those adequate warnings;

C. Insufficiently alerting Plaintiff and Plaintiff's treating physician about the dangers that the Devices at issue posed to consumers, including the risk of adverse events or complications, subjecting Plaintiff to risks which exceeded the benefits of the Devices at issue;

D. Containing misleading warnings emphasizing the safety and efficacy of the Devices at issue, while downplaying the risks associated with it, thereby making use of the Devices at issue more dangerous than the ordinary consumer would expect;

E. Containing insufficient and/or incorrect warnings to alert consumers, including Plaintiff, through her implanting physician, regarding risk, scope, duration, and severity of the adverse events and/or complications associated with the Devices at issue;

F. Failing to disclose the fact that the Devices at issue were inadequately tested;

G. Failing to convey adequate post-market warnings regarding the risk, severity, scope and/or duration of the dangers posed by the Devices at issue; and

H. Failing to contain instructions sufficient to alert consumers to the dangers posed by the Devices at issue.

82. Plaintiff used the Devices at issue for their intended purpose.

83. Neither Plaintiff nor her implanting physician could have discovered any defect in the Devices at issue through the exercise of due care.

84. Defendants, as designer, manufacturer, marketer, and distributor of pelvic mesh products, are held to the level of knowledge of an expert in their field.

85. Plaintiff and her implanting physician did not have substantially the same knowledge as Defendants – the designer, manufacturer, marketer, and distributor of the Devices at issue.

86. As a direct and proximate result of one or more of these wrongful acts or omissions made by the Defendants, Plaintiff has suffered and continues to suffer devastating injuries and damages and continues to require medical treatment due to these injuries.

WHEREFORE, said Plaintiff prays for judgment against Defendants.

COUNT III: STRICT LIABILITY – NON-SPECIFIC DEFECT

87. Additionally, or in the alternative, if same be necessary, Plaintiff re-alleges and incorporates by reference each of the foregoing paragraphs 1 through 86 of this Complaint as if fully set forth herein and further alleges as follows:

88. Defendants had a duty to place into the stream of commerce, manufacture, distribute, market, promote, and sell the Devices in a manner that was not defective and not unreasonably dangerous when put to the use for which it was designed, manufactured, distributed, marketed, and sold.

89. Defendants did in fact sell, distribute, supply and/or promote the Device to Plaintiff and her implanting physician.

90. Defendants expected that the Devices it was selling, distributing, supplying, manufacturing, and/or promoting to reach, and it did in fact reach, implanting physicians and consumers in the States of Minnesota and North Carolina, including Plaintiff and her implanting physician, without substantial change in their condition.

91. At the time the Devices left the possession of Defendants and the time the Devices entered the stream of commerce, the Devices were in an unreasonably dangerous, unsafe, and defective condition. These defects include, but are not limited to, the following:

A. By posing an unreasonably high probability of complications and/or injuries to the user, the Devices did not perform in a manner reasonably to be expected in light of their nature and intended function;

B. The Devices failed to perform in a manner reasonably expected in light of their nature and intended function, and subjected Plaintiff to an unreasonable risk of harm beyond that contemplated by an ordinary person; and

C. The Devices otherwise possessed a condition which made them unreasonably dangerous for its intended and foreseeable use.

92. Plaintiff used the Devices for their intended purpose.

93. Neither Plaintiff nor her implanting physician could have discovered any defect in the Devices through the exercise of due care.

94. Defendants, as designer, manufacturer, marketer, and distributor of pelvic mesh products are held to the level of knowledge of an expert in their field.

95. Plaintiff and her implanting physician did not have substantially the same knowledge as Defendants – the designer, manufacturer, marketer, and distributor of the Devices.

96. As a direct and proximate result of one or more of these wrongful acts or omissions of Defendants, Plaintiff has suffered and continues to suffer devastating injuries and damages and continues to require medical treatment due to these injuries.

WHEREFORE, said Plaintiff prays for judgement against Defendants.

COUNT III: FRAUD

97. Additionally, or in the alternative, if same be necessary, Plaintiff re-alleges and incorporates by reference each of the foregoing paragraphs 1 through 96 of this Complaint as if fully set forth herein and further alleges as follows:

98. Under Minnesota law, the elements of common law fraud are: (1) false statement of material fact; (2) known or believed to be false, or ignorance of the truth by the party making it; (3) intent to induce the other party to act; (4) action by the other party in [justifiable] reliance on the truth of the statement; and (5) damage to the other party resulting from such reliance. *Martens v. Minnesota Mining & Mfg. Co.*, 616 N.W.2d 732,747 (Minn. 2000)

99. Defendants were and are engaged in the business of selling their Pelvic Mesh Products, including the Devices aforementioned, in the States of Minnesota and North Carolina.

100. The Devices, manufactured, designed, marketed, promoted, and sold by Defendants, were expected to, and did, reach Plaintiff and her treating physician without substantial change in the condition in which it was sold. The Device was defective at the time of manufacture, development, design, production, testing, inspection, endorsement, prescription, sale, and distribution, and at the time it left the possession of the Defendants.

101. At the time Defendants' Pelvic Mesh Products, specifically the Devises at issue, left the possession of Defendants and entered the stream of commerce, the Devices at issue were in an unreasonably dangerous and defective condition.

102. Defendants knew of should have known that their Pelvic Mesh Products unreasonably exposed patients to the risk of serious harm while conferring no benefit over available feasible alternatives that do not involve the same risks.

103. Defendants knew, or should have known, that their warnings were insufficient to fully put Plaintiff and Plaintiff's implanting physician on notice of the potential dangers and risks of the Devices by failing to inform them of the following material facts:

A. Defendants' Pelvic Mesh Products, specifically the Devices at issue, created, among other things, erosion, mesh contraction, infection, fistula, inflammation, scar tissue, organ perforation, dyspareunia (pain during sexual intercourse), blood loss, neuropathic pain, and other acute and chronic nerve damage and pain, nerve damage, pelvic floor damage, and chronic pelvic pain;

B. Defendants' Pelvic Mesh Products, specifically the Devices at issue, were inadequately tested;

C. Defendants' Pelvic Mesh Products, specifically the Devices at issue, could be harmful to humans;

D. Defendants' Pelvic Mesh Products, specifically the Devices at issue, posed extreme risks of adverse events or complications; and

E. Defendants' Pelvic Mesh Products, specifically the Devices at issue, subject consumers, such as Plaintiff, to risks which exceed the benefits of the Devices.

104. Additionally, Defendants knew, or should have known, that their warnings were misleading and/or inaccurate due to the following:

A. Defendants failed to provide adequate initial warnings and post-marketing warnings or instructions after Defendants knew or should have known of the extreme risks associated with their Pelvic Mesh Products, including the Devices at issue;

B. Defendants' warnings misled consumers by emphasizing the safety and efficacy of the Devices at issue, while downplaying the risks associated with them, thereby making the use of the Devices at issue more dangerous than the ordinary consumer would expect; and

C. Defendants' warnings contained insufficient and/or incorrect information to alert consumers, including Plaintiff, through her implanting physician, regarding the risk, scope, duration, and severity of the adverse events and/or complications associated with the Devices at issue.

105. Defendants knew, or should have known, that their insufficient, misleading, and inaccurate warnings would induce consumers, including Plaintiff and her implanting physician, to rely on them when evaluating whether to use Defendants' Pelvic Mesh Products, including the Devices at issue, as the appropriate course of treatment for stress urinary incontinence and/or pelvic organ prolapse.

106. Defendants, as designer, manufacturer, marketer, and distributor of pelvic mesh products, are held to the level of knowledge of an expert in their field.

107. Plaintiff and her implanting physician did not have substantially the same knowledge as Defendants – the designer, manufacturer, marketer, and distributor of the Devices.

108. Neither Plaintiff nor her implanting physician could have discovered any defect in the Devices through the exercise of due care.

109. As a direct and proximate result of one or more of these wrongful acts or omissions of Defendants, Plaintiff has suffered and continues to suffer devastating injuries and damages and continues to require medical treatment due to these injuries.

WHEREFORE, said Plaintiff prays for judgement against Defendants.

COUNT IV: CONSUMER FRAUD ACT

110. Additionally, or in the alternative, if same be necessary, Plaintiff re-alleges and incorporates by reference each of the foregoing paragraphs 1 through 109 of this Complaint as if fully set forth herein and further alleges as follows:

111. Under the Minnesota Consumer Fraud Act, defines as unlawful "The act, use, or employment by any person of any fraud, false pretense, false promise, misrepresentation, misleading statement or deceptive practice, with the intent that others rely thereon in connection with the sale of any merchandise. Minn. Stat. 325F.69.

112. To state a claim, "the plaintiff need only plead that the defendant engaged in conduct prohibited by the statutes and that the plaintiff was damaged thereby." Grp. Health Plan, Inc. v. Philip Morris, Inc., 621 N.W.2d 2,12 (Minn. 2001).

113. The conduct of Defendants clearly caused "substantial injury to" Plaintiff, due to their failure to alert Plaintiff and her implanting physician of the adverse events associated with their Pelvic Mesh Products, including the Devices at issue, which, Defendants knew, or should have known, would lead to "substantial injury" amongst women, including Plaintiff, that were implanted with Defendants' Pelvic Mesh Products, including the device at issue.

114. The adverse events known to Defendants in July of 2011 through the FDA's safety communication include, but are not limited to, the following:

A. Polypropylene mesh can cause chronic inflammation of the pelvic tissue, shrinkage or contraction of the mesh leading to nerve entrapment, further inflammation, chronic infectious response and chronic pain, cause new-onset painful sexual relations, significant urinary dysfunction, vaginal shortening and anatomic deformation, and can contribute to the formation of severe adverse reactions to the polypropylene mesh;

B. Erosion of mesh through the vagina is the most common and consistently reported mesh-related complication from transvaginal POP surgeries using mesh;

C. Mesh erosion can require multiple surgeries to repair and can be debilitating for women; and

D. Surgery or multiple surgeries may not resolve the complications caused by mesh erosion.

115. Defendants, despite their knowledge of the above risks and complications that their Pelvic Mesh Products, including the Devices at issue, can cause, continued to promote their Pelvic mesh Products, including the Devices at issue, on websites aimed at creating user and consumer demand as safe and/or safer than other comparative products.

116. For the reasons aforementioned, Defendants participated in acts and practices that caused Plaintiff "substantial injury" to such a degree that Defendants' acts and practices were unfair within the meaning of the aforementioned Minnesota Consumer Fraud Act.

117. Therefore, Defendants violated the Minnesota Consumer Fraud Act, making them liable to Plaintiff for the substantial and debilitating injuries, symptoms and conditions suffered by Plaintiff due to such violation.

WHEREFORE, said Plaintiff prays for judgment against Defendants.

PRAYER FOR RELIEF

WHEREFORE, Plaintiff demands trial by jury, and prays for judgment against Defendants individually, jointly, and severally and requests compensatory damages, together with interest, cost of suit, attorneys' fees, and all such other relief as the Court deems just and proper as well as:

1. For past and future general damages, the exact amount of which has yet to be ascertained, in an amount which will conform to proof at time of trial;
2. For past and future economic and special damages, according to proof at the time of trial;
3. For past and future medical and incidental expenses, according to proof at the time of trial;
4. For past and future loss of earnings and impaired earning capacity, according to proof at the time of trial; and
5. For past and future mental and emotional distress, according to proof at the time of trial.
6. For costs, attorneys' fees, interest, or any other relief, monetary or equitable, to which she is entitled; and
7. For such other and further relief as the Court may deem just and proper.

DEMAND FOR JURY TRIAL

Plaintiff hereby demands trial by jury as to all issues in the above-captioned matter.

Dated: January 13, 2022

FEARS NACHAWATI LAW FIRM, PLLC

/s/ Gale D. Pearson
Gale D. Pearson, Esq.
MN Bar No. 244673
Fears Nachawati Law Firm
5489 Blair Road
Dallas, TX 75231
(214) 890-0711 Phone
(469) 914-7724 Fax
gpearson@fnlawfirm.com

To be admitted Pro hac Vice:

/s/ Danae N. Benton
Danae N. Benton
TX Bar No. 24080422
5489 Blair Road
Dallas, TX 75231
Tel: 214-890-0711
Fax: 214-890-0712
dbenton@fnlawfirm.com

ATTORNEYS FOR PLAINTIFF